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Sent: 9/13/2023 1:43:38 PM
From: Patrick Boland <Boland
To: "Howard"
Cc:
Bcc:
Importance: Normal
Subject: FW: NRG GI005 abstract - ASCO GI submission
Attachments: NRG GI005 abstract - 9-8-2023.docx

Here's what I know, from 1st circulated draft of abstract – obviously not for sharing outside here. Would be interested to hear what else is happening.

Definitely some issues they have with the assay as it was performed/analyzed.

Pat

From: Morris, Van Karlyle <VKMorris@mdanderson.org>
Sent: Friday, September 8, 2023 1:54 PM
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Cc: Gwen Rea <wendy.rea@nsabp.org>; Fonzi, Francy <FonziF@nrgoncology.org>
Subject: NRG GI005 abstract - ASCO GI submission

Hi all-

I wanted to circulate an abstract for your review that summarizes the phase II analysis for the GI005 study. I apologize for the quick timeline here, but if you could please respond with any comments by next Weds AM to Thom and me, that would be great. Wendy and Francy, could you send this to the CTEP and Guardant teams for their review? The deadline for submission for the conference is Tuesday 9/19.

As a reminder, under contractual obligations with the NCI, we are all embargoed from sharing this abstract or discussing results reported here with anyone outside of the coauthors included in this email. Specifically, you cannot discuss this with colleagues, bosses, people within your cooperative group, etc. I am sure that, like me, you have been getting emails and questions from outside people asking what is going on here, and because many discussions have been going on behind the scenes between NRG, CTEP, and Guardant following the NCI's decision last week, it is essential not to speak about this with anyone else.

I know that we have a study team meeting next Tuesday- let's plan on keeping that meeting and we can talk more then. Have a good weekend,
Van

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Phase II results of Circulating tumor DNA as a predictive Biomarker in Adjuvant chemotherapy in patients with stage II colon cancer - NRG-GI005 (COBRA) Phase II/III Study

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Introduction: For patients (pts) with colon cancer (CC), the detection of circulating tumor DNA (ctDNA) is associated with persistent disease after resection and outperforms traditional clinical and pathological features in prognosticating recurrence risk. We hypothesized that for pts with low-risk stage II CC, a positive ctDNA status after resection may identify those who benefit from adjuvant chemotherapy.

Methods: In this prospective phase II/III clinical trial, pts with resected stage II CC without traditional high-risk features and whom the evaluating oncologist deems suitable for active surveillance (i.e., not needing adjuvant chemotherapy) were randomized 1:1 into 2 arms: standard-of-care/observation (Arm A), or prospective testing for ctDNA (Arm B). Postoperative blood was analyzed for ctDNA with the Guardant LUNAR assay, covering CC-relevant mutations and CC-specific methylation profiling. Pts in Arm B with ctDNA detected were treated with 6 months of adjuvant (CAPOX or FOLFOX) chemotherapy. The primary endpoint for the phase II study was clearance of ctDNA with adjuvant chemotherapy. A 1-sided Fisher exact test was used to compare ctDNA clearance after 6 months between 16 pts in Arm A and Arm B with ctDNA detected. If $p > .35$, the study would be stopped for futility of ctDNA clearance, but would otherwise continue to the phase III study if $p \leq .35$. Here we present the results of the pre-planned phase II analysis.

Results: 635 pts were randomized (Arm A- 318; Arm B- 317) at the time of the analysis. One pt with ctDNA detected in Arm 2 declined protocol-directed chemotherapy. Among the 16 pt with ctDNA detected at baseline for the primary endpoint analysis, clearance of ctDNA after 6 months was observed in 3 of 7 pts (43%, 95% CI 10-82%) in the control arm and in 1 of 9 pts (11%, 95% CI 0.3-48%) in the experimental arm after chemotherapy ($p=.98$). There were no unanticipated toxicities in those treated with chemotherapy. In an unplanned post-hoc analysis utilizing a refined monitoring script which improved CHIP identification and filtered out methylation-only calls in samples with high cell-free DNA, a "ctDNA detected" status was observed in 12 of the 16 pts at baseline. In this subset, clearance of ctDNA after 6 months occurred in 1 of 5 pts (20%) in the control arm and in 4 of 7 pts (57%) in the chemotherapy arm ($p=.25$).

Conclusions: The phase II endpoint was not met and further enrollment has been halted based upon pre-specified study stopping rules. No improvement in ctDNA clearance was observed after 6 months of chemotherapy for pts with ctDNA detected following resection of stage IIA CC in this study. Future trials evaluating ctDNA as an integral biomarker for minimal residual disease determination must account for assay specificity in this patient population.